



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
David Yang *et al.*

Serial No.: 09/599,152

Filed: June 21, 2000

For: ETHYLENEDICYSTEINE (EC)-DRUG CONJUGATES, COMPOSITIONS AND METHODS FOR TISSUE SPECIFIC DISEASE IMAGING

Group Art Unit: 1645

Examiner: Dameron Levest Jones

Atty. Dkt. No.: UTSC:664

CERTIFICATE OF MAILING 37 C.F.R 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Attn.: Dameron Levest Jones, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:	
March 29, 2004	Date
David L. Parker	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Attn.: Dameron Levest Jones
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

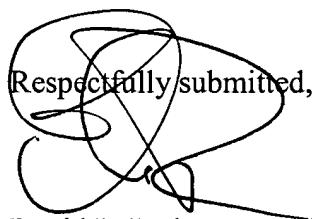
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construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/UTSC:664.

Applicants respectfully request that the listed documents be made of record in the present case.


Respectfully submitted,

David L. Parker
Reg. No. 32,165
Attorney for Applicants

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Date: March 29, 2004

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David Yang, Chun-Wei Liu, Dong-Fang Yu and E.
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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A14	2001/0034363	10/25/01	Li <i>et al.</i>	514	449	3/30/98
	A15	2001/0041189	11/15/01	Xu	424	488	4/13/99
	A16	4,418,068	11/29/83	Jones	424	267	12/16/81
	A17	4,507,466	3/26/85	Tomalia <i>et al.</i>	528	332	1/07/83
	A18	4,558,120	12/10/85	Tomalia <i>et al.</i>	528	363	12/27/83
	A19	4,568,737	2/04/86	Tomalia <i>et al.</i>	528	332	8/17/84
	A20	4,587,329	5/06/86	Tomalia <i>et al.</i>	528	363	7/19/85
	A21	4,631,337	12/23/86	Tomalia <i>et al.</i>	528	391	7/115/85
	A22	4,694,064	9/15/87	Tomalia <i>et al.</i>	528	332	2/28/86
	A23	4,713,975	12/22/87	Tomalia <i>et al.</i>	73	864.8	5/30/86
	A24	4,732,863	3/22/88	Tomasi <i>et al.</i>	436	547	12/31/84
	A25	4,737,550	4/12/88	Tomalia	525	419	12/08/86
	A26	4,857,599	8/15/89	Tomalia <i>et al.</i>	525	259	2/08/88
	A27	4,871,779	10/03/89	Killat <i>et al.</i>	521	28	12/23/85
	A28	5,087,616	2/11/92	Myers <i>et al.</i>	514	21	8/06/87
	A29	5,164,294	11/17/92	Skold <i>et al.</i>	435	7.5	7/07/89
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	A31	5,534,241	7/09/96	Torchilin <i>et al.</i>	424	9.321	7/23/93
	A32	5,605,671	2/25/97	Lyle <i>et al.</i>	424	1.41	4/29/94
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	A35	5,830,431	11/03/98	Srinivasan <i>et al.</i>	424	1.69	6/07/95
	A36	5,908,777	6/01/99	Lee <i>et al.</i>	435	320.1	3/23/95

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Form PTO-1449 (modified)		Atty. Docket No. UTSC:664	Serial No. 09/599,152
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicants David Yang, Chun-Wei Liu, Dong-Fang Yu and E. Edmund Kim	
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	A37	5,977,163	11/02/99	Li <i>et al.</i>	514	449	3/11/97
	A38	6,071,533	6/06/00	Papahadjopoulos <i>et al.</i>	424	450	11/17/95
	A39	6,083,741	7/04/00	Hart <i>et al.</i>	435	320.1	11/17/95
	A40	6,113,946	9/05/00	Szoka, Jr. <i>et al.</i>	424	486	6/06/95
	A41	6,251,866	6/26/01	Prakash <i>et al.</i>	514	17	8/04/98
	A42	6,262,107	7/17/01	Li <i>et al.</i>	514	449	7/01/99
	A43	5,517,993	5/21/96	Unger and Wu	128	653.4	6/07/95

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Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 95/28966	11/02/95	PCT			
	B2	WO 97/33552	9/18/97	PCT			
	B3	WO 99/39748	8/12/99	PCT			
	B4	WO 99/49901	10/07/99	PCT			
	B5	WO 99/61512	12/02/99	PCT			
	B6	WO 00/53233	9/14/00	PCT			
	B7	WO 00/61788	10/19/00	PCT			

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	C147	Anderson <i>et al.</i> , "Radiometal-labeled agents (non-technetium) for diagnostic imaging," <i>Chem. Rev.</i> , 99:2219-2234, 1999.
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	C149	Aoi <i>et al.</i> , "Globular carbohydrate macromolecule 'sugar balls' 3. 'radical-growth polymerization' of sugar-substituted α -amino acid N-carboxyanhydrides (glycoNCAs) with a dendritic initiator," <i>Tetrahedron, Elsevier Science Publishers</i> , 53(45):15415-15427, 1997.
	C150	Bajorin <i>et al.</i> , <i>Proc. Annu. Meet. Am. Soc. Clin. Oncol.</i> , 7:250, A967, 1988.
	C151	Baselga <i>et al.</i> , "Phase I studies of anti-epidermal growth factor receptor chimeric antibody C225 alone and in combination with cisplatin," <i>J. Clinical Oncology</i> , 18(4):904-914, 2000.
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	C154	Blackenberg <i>et al.</i> , "Apoptosis: the importance of nuclear medicine," <i>Nucl. Med. Comm.</i> , 21:241-250, 2000.
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	C160	Brogi <i>et al.</i> , "Hypoxia-induced paracrine regulation of vascular endothelial growth factor receptor expression," <i>J. Clin. Invest.</i> , 97(2):469-476, 1996.
	C161	Brokx <i>et al.</i> , "Designing peptide-based scaffolds as drug delivery vehicles," <i>Science</i> , 78(1-3):115-123, 2002.

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List of Patents and Publications for Applicant's

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	C162	Budihardjo <i>et al.</i> , "Biochemical pathways of caspase activation during apoptosis," <i>Annu. Rev. Cell Dev. Biol.</i> , 15:269-290, 1999.
	C163	Burgen, "Targets of drug action," <i>Ann. Rev. Pharmacol. Toxicol.</i> , 40:1-16, 2000.
	C164	Chapman <i>et al.</i> , "Therapeutic antibody fragments with prolonged in vivo half-lives," <i>Nature Biotech.</i> , 17:780-783, 1999.
	C165	Collier <i>et al.</i> "Immunoscintigraphy performed with In-111-labeled CYT-103 in the management of colorectal cancer: comparison with CT," <i>Radiology</i> , 185:179-186, 1992.
	C166	Culver <i>et al.</i> , "In vivo gene transfer with retroviral vector-producer cells for treatment of experimental brain tumors," <i>Science</i> , 256:1550-1552, 1992.
	C167	Deguchi <i>et al.</i> , "Retention of biologic activity of human epidermal growth factor following conjugation to a blood-brain barrier drug delivery vector via an extended poly(ethylene glycol) linker," <i>Bioconjugate Chem.</i> , 10:32-37, 1999.
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	C170	Deutsch <i>et al.</i> , "Synthesis of congeners and prodrugs, water-soluble prodrugs of taxol with potent antitumor activity," <i>J. Med. Chem.</i> , 32:788-792, 1989.
	C171	Divgi <i>et al.</i> , "Phase I and imaging trial of indium 111-labeled anti-epidermal growth factor receptor monoclonal antibody 225 in patients with squamous cell lung carcinoma," <i>J. National Cancer Institute</i> , 83(2):97-104, 1991.
	C172	Drobnik <i>et al.</i> , "Soluble synthetic polymers in biological systems," <i>Adv. Polym. Sci.</i> , 57:1-50, 1984.
	C173	Dunn <i>et al.</i> , "Receptor-mediated endocytosis of epidermal growth factor by hepatocytes in the perfused rat liver: ligand and receptor dynamics," <i>J. Cell Biol.</i> , 98:2148-2159, 1984.
	C174	Eary <i>et al.</i> , "Radiochemistry of halogenated antibodies," <i>Antibodies in Radiodiagnosis and Therapy</i> , Boca Raton, Florida, CPC Press, 83-100, 1988.

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O I P E
P A T E N T & T R A D E M A R K S O U R C E
S C E N T R A L
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	C175	Eiseman <i>et al.</i> , "Plasma pharmacokinetics and tissue distribution of paclitaxel in CD2F1 mice," <i>Cancer Chemother. Pharmacol.</i> , 34:465-471, 1994.
	C176	Ennis <i>et al.</i> , "Anti-epidermal growth factor receptor antibodies inhibit the autocrine-stimulated growth of MDA-468 human breast cancer cells," <i>Mol. Endocrinology</i> , 3(11):1830-1838, 1989.
	C177	Ethier, "Growth factor synthesis and human breast cancer progression," <i>J. Natl. Cancer Inst.</i> , 87(13):964-973, 1995.
	C178	Fan <i>et al.</i> , "Antitumor effect of anti-epidermal growth factor receptor monoclonal antibodies plus cis-diamminedichloroplatinum on well established A431 cell xenografts," <i>Cancer Research</i> , 53:4637-4642, 1993.
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	C180	Fang <i>et al.</i> , "Involvement of p21 Waf1 in mediating inhibition of paclitaxel-induced apoptosis by epidermal growth factor in MDA-MB-468 human breast cancer cells," <i>Anticancer Research</i> , 20(1A):103-112, 2000.
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	C183	Frankel <i>et al.</i> , "Targeted toxins," <i>Clin. Cancer Res.</i> , 6:326-334, 2000.
	C184	Fuertges <i>et al.</i> , "The clinical efficacy of poly(ethylene glycol)-modified proteins," <i>J. Controlled Release</i> , 11:139-148, 1990.
	C185	Fuller <i>et al.</i> , "A procedure for the facile synthesis of amino-acid N-carboxyanhydride," <i>Biopolymers</i> , 15:1869, 1976.
	C186	Gabizon, "Selective tumor localization and improved therapeutic index of anthracyclines encapsulated in long-circulating liposomes," <i>Cancer Research</i> , 52:891-896, 1992.
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	C189	Goldenberg <i>et al.</i> , "Imaging of human tumor xenografts with and indium-111-labeled anti-epidermal growth factor receptor monoclonal antibody," <i>J. National Cancer Institute</i> , 81:1616-1625, 1989.
	C190	Goldenberg, "Monoclonal antibodies in cancer detection and therapy," <i>Am. J. Med.</i> , 94:297-312, 1993.
	C191	Goldspeil, "Pharmaceutical issues: preparation, administration, stability, and compatibility with other medications," <i>Ann. Pharmacother.</i> , 28:S23-S26, 1994.
	C192	Gonda, "Aerosols for delivery of therapeutic and diagnostic agents to the respiratory tract," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 6(4):273-313, 1990.
	C193	Greenfield <i>et al.</i> , "In vitro evaluation of immunoconjugates prepared by linking mitomycin C to monoclonal antibodies via polyglutamic acid carriers," <i>Antibody, Immunoconjugates, and Radiopharmaceuticals</i> , 2(3):201-216, 1989.
	C194	Greenwald <i>et al.</i> , "Drug delivery systems: water soluble tazol 2'-poly(ethylene glycol) ester prodrugs design and in vivo effectiveness," <i>J. Med. Chem.</i> , 39:424-431, 1996.
	C195	Halpern <i>et al.</i> , "Stability, characterization, and kinetics of In-labeled monoclonal antitumor antibodies in normal animals and nude mouse human tumor models," <i>Cancer Research</i> , 43:5347-5355, 1983.
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	C197	Hermanson, "Ellman's assay for the determination of sulfhydryls," <i>Bioconjugate Techniques</i> , San Diego, Academic Press, 88-90, 1996.
	C198	Hnatowich <i>et al.</i> , "Radioactive labeling of antibody: a simple and efficient method," <i>Science</i> , 220:613-615, 1983.
	C199	Hoes <i>et al.</i> , "Optimization of macromolecular prodrugs of the antitumor antibiotic adriamycin," <i>J. Controlled Release</i> , 2:205-213, 1985.

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	C200	Holmes <i>et al.</i> , "Current status of clinical trials with paclitaxel and docetaxel, taxane anticancer agents: basic science and current status," <i>American Chemical Society</i> , Washington, DC, 31-57, 1995.
	C201	Hudecz <i>et al.</i> , "Influence of carrier on biodistribution and in vitro cytotoxicity of methotrexate-branched polypeptide conjugates," <i>Bioconjugate Chemistry</i> , American Chemical Society, 4(1):25-33, 1993.
	C202	Inoue <i>et al.</i> , "Paclitaxel enhances the effects of the anti-epidermal growth factor receptor monoclonal antibody ImClone C225 in mice with metastatic human bladder transitional cell carcinoma," <i>Clinical Cancer Res.</i> , 6:4874, 4884, 2000.
	C203	Irie <i>et al.</i> , "Regression of cutaneous metastatic melanoma by inralesional injection with human monoclonal antibody to ganglioside GD2," <i>Proc. Natl. Acad. Sci., USA</i> , 83:8694-8698, 1986.
	C204	Jeppesen <i>et al.</i> , "Impact of polymer tether length on multiple ligand-receptor bond formation," <i>Science</i> , 293:465-468, 2001.
	C205	Jurisson <i>et al.</i> , "Potential technetium small molecule radiopharmaceuticals," <i>Chem. Rev.</i> , 99:2205-2218, 1999.
	C206	Kato and Sugiyama, "Targeted delivery of peptides, proteins, and genes by receptor-mediated endocytosis," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 14(3):287-331, 1997.
	C207	Kato <i>et al.</i> , "A novel method of conjugation of daunomycin with antibody with a poly-L-glutamic acid-a-fetoprotein antibody-daunomycin conjugate," <i>J. Med. Chem.</i> , 27:1602-1607, 1984.
	C208	Kitamura <i>et al.</i> , "Chemical engineering of the monoclonal antibody A7 by polyethylene glycol for targeting cancer chemotherapy," <i>Cancer Research</i> , 51:4310-4315, 1991.
	C209	Klok <i>et al.</i> , "Star-shaped fluorescent polypeptides," <i>Journal of Polymer Science</i> , 39(10):1572-1582, 2001.
	C210	Kopecek <i>et al.</i> , "Targetable water-soluble polymeric anticancer drugs: achievements and unsolved problems," <i>Proc. Intern. Symp. Conol. Rel. Bioact. Mater.</i> , 20:190-191, 1993.
	C211	Kopecek <i>et al.</i> , "Targetable polymeric prodrugs," <i>J. Control. Release</i> , 6:315-327, 1987.
	C212	Kopecek, "The potential of water-soluble polymeric carriers in targeted and site-specific drug delivery," <i>Journal of Controlled Release</i> , 11:279-290, 1990.

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Edmund Kim

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